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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,420	12/08/2003	Timothy M. Woudenberg	4320 C1	3941

7590 10/11/2007
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EXAMINER

VATHYAM, SUREKHA

ART UNIT	PAPER NUMBER
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1795

MAIL DATE	DELIVERY MODE
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10/11/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/731,420

Applicant(s)

WOUDENBERG ET AL.

Examiner

Surekha Vathyam

Art Unit

1795

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/3/07 & 8/10/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: Page 1, line 2, after "2000," insert - -now US Patent No. 6,660,147,- -.

Appropriate correction is required.

Terminal Disclaimer

2. The terminal disclaimer filed on 26 July 2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 6,660,147 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 24 – 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 24 recites the limitation "the one or more chambers" in line 17. There is insufficient antecedent basis for this limitation in the claim. Claim 24 recites "a first chamber" and "a second chamber" in lines 9 and 11 respectively. The claim therefore requires at least two chambers. For purposes of examination, the limitation will be

interpreted as requiring "one or more chambers" in addition to the first chamber and second chamber.

6. Dependent claims 25, 36 and 38 each make reference to "the one or more chambers" of claim 24 and dependent claims 31 and 32 each make reference to "said chambers" of claim 24. It is unclear which of the many chambers recited in claim 24 are being referred to in these dependent claims.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 24 – 30, 33 and 35 – 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Place et al. (US 4,715,943) in view of Place et al. (US 4,652,354).

Regarding claim 24, Place ('943) discloses an analytical system (see fig. 1) comprising: a substrate including a central reservoir region (40a), a plurality of electrophoretic channels in fluid communication with, and emanating substantially radially from, the central reservoir region, the channels being coplanar with each other (column 5, lines 3 – 14), and each channel having a proximal end (17) which is linked to the central reservoir region, and a distal end (16), a mechanism for rotating the substrate about a central axis of rotation that is perpendicular to the plane of the channels (45); and a plurality of electrodes (42a and 42b) for applying a voltage potential between one or more chambers (40b) and the central reservoir region. Place ('943) does not explicitly disclose a separate chamber linked by a passageway to each channel. Place ('943) however, discloses a first of the plurality of electrophoretic channels can incorporate a sample that is different from a second of the plurality of electrophoretic channels (column 9, lines 3 – 8). Place ('943) also discloses samples can be incorporated into electrophoretic channels by special openings in the vicinity of

an end of each channel, the details of such openings being disclosed in U.S. Patent No. 4,652,354 to Place et al. (column 8, lines 44 – 53).

Place ('354) teaches an analytical system (see figs. 1 – 7 and column 1, lines 6 – 8) comprising: a central reservoir region (15), a plurality of electrophoretic channels (12) in fluid communication with, and emanating substantially radially from, the central reservoir region, the channels being coplanar with each other (see fig. 3 and column 6, lines 19 – 38), and each channel having a proximal end which is linked to the central reservoir region, and a distal end (see figs. 3 and 4), a mechanism for rotating the substrate about a central axis of rotation (17) that is perpendicular to the plane of the channels (column 6, lines 44 – 51 and column 7, lines 10 – 17). Place ('354) teaches separate chambers linked by a passageway such as the recesses created by pegs (24) via openings (23) in the vicinity of an end of each of the plurality of electrophoretic channels (12) that could have any shape for incorporating a sample (see figs. 3 and 4 and column 6, line 57 – column 7, line 38).

It would have been exceedingly obvious to one of ordinary skill in the art to have combined the disclosure of Place ('943) with the teachings of Place ('354) to have separate chambers linked by a passageway to each electrophoretic channel because of the specific statement of Place ('943) in column 8, lines 44 – 53 to do so and also because it provides the benefit of incorporating different samples in each of the electrophoretic channels as explained by Place ('943) (column 9, lines 3 – 8).

Regarding claim 25, Place ('943) discloses the system whereby centrifugation of the substrate about the central axis is effective to disperse liquid from the central reservoir region into the channels and the one or more chambers such that any air bubbles in the one or more chambers, the channels, and the passageways are forced towards the axis of rotation, when such liquid is present in the central reservoir region (column 8, lines 31 – 37).

Regarding claim 26, Place ('943) discloses the system further comprising a contact card adapted to supply separate electrical voltages to the electrodes (see figs. 1, 5 and 6 and column 6, lines 27 – 34 and column 6, line 63 – column 7, line 2).

Regarding claim 27, Place ('943) discloses the system further comprising: conductive concentric rings (43a, 43b and 64) in electrical contact with the electrodes; and conductive brushes (44, 65a and 65b) which remain in contact with the concentric rings, when the substrate is rotated.

Regarding claim 28, Place ('943) discloses the system further comprising a voltage source adapted to independently control each of the plurality of electrodes (see column 9, lines 19 – 36).

Regarding claim 29, Place ('943) discloses the system further comprising a detector (72) for detecting selected components which may be present in one or more of the channels.

Regarding claim 30, Place ('943) discloses the system wherein the mechanism for rotating the substrate about the central axis is adapted to sequentially pass the

channels by the detector, for detecting one or more components that may be present in the channels (column 7, lines 4 – 22).

Regarding claim 33, Place ('943) discloses the system wherein at least one of the channels contains an electrophoresis medium (column 8, lines 14 – 43).

Regarding claim 35, Place ('943) discloses the system further comprising a temperature controller adapted to selectively heat or cool on or more surfaces of the substrate (column 9, lines 19 – 22).

Regarding claim 36, Place ('943) discloses the system wherein the temperature controller is adapted to heat the one or more chambers of each channel (column 9, lines 19 – 22).

Regarding claim 37, Place ('943) discloses the system wherein the substrate comprises a material comprising at least one of copper, aluminum, glass, silica-based glass, quartz, and polycarbonate (column 7, lines 25 – 28).

Regarding claim 38, Place ('943) discloses the system wherein the substrate further comprises electrical resistive traces in thermal contact with the one or more chambers of each channel (see figs. 1, 5 and 6).

11. Claims 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Place et al. (US 4,715,943) in view of Place et al. (US 4,652,354) as applied to claim 24 above, and further in view of Chan (US 4,973,168).

Regarding claims 31 and 32, Place ('943) in view of Place ('354) discloses the system wherein said chambers are defined in part by an annular partition (41) that covers the chambers. Place ('943) further discloses a special opening for delivery of liquid to the chambers (column 8, lines 44 – 53) (claim 31) and that displaced air escapes when liquid is loaded into the channels (column 8, lines 31 – 37) (claim 32).

Place ('943) in view of Place ('354) does not explicitly disclose the opening to be covered by a septum.

Chan ('168) teaches a chamber (5) defined in part by an annular septum (37) that covers the chamber and permits needle-access (83) to the chamber for delivery of liquid to the chambers (column 12, lines 1 – 6) (claim 31). Chan ('168) also teaches the septum is porous to air, such that displaced air escapes through the septum (column 12, lines 44 – 46) (claim 32).

It would have been obvious to one of ordinary skill in the art to modify the system of Place ('934) in view of Place ('354) comprising the special opening with a septum as taught by Chan ('168) because it would permit the release of pressure within the chamber as explained by Chan ('168) (column 12, lines 44 – 46).

12. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Place et al. (US 4,715,943) in view of Place et al. (US 4,652,354) as applied to claim 24 above, and further in view of Mian et al. (US 6,319,469).

Regarding claim 34, Place ('943) in view of Place ('354) does not explicitly disclose the cross-sectional diameter of the channels.

Mian ('469) discloses a system comprising radial channels (see fig. 18) wherein the channels have cross-sectional diameters between 1 μm and 100 μm (column 8, lines 30 – 53 and see examples).

It would have been obvious to one of ordinary skill in the art to modify the system of Place ('934) in view of Place ('354) to have the channels have a cross-sectional diameter as taught by Mian ('469) because as Mian ('469) explains that the size of the channel is optimally determined by specific applications and amount of reagent and reagent delivery rates required for each particular application (column 8, lines 30 – 34).

13. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Place et al. (US 4,715,943) in view of Place et al. (US 4,652,354) as applied to claim 24 above, and further in view of Stewart (US 5,313,129).

Regarding claim 39, Place ('943) in view of Place ('354) discloses the system wherein the mechanism (45) comprises a motor shaft to rotate the substrate, and wherein the motor shaft is adapted to be in communication with a liquid disposed in the central reservoir region (see figs. 1 and 5 and column 6, lines 33 – 36).

Place ('943) in view of Place ('354) does not explicitly disclose the motor shaft is electrically grounded.

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It would have been obvious to one of ordinary skill in the art to have electrically grounded the motor shaft of Place ('934) in view of Place ('354) because it is notoriously well known to do so as explained by Stewart ('129) to prevent the flow of electrical current through the shaft to equipment which are attached to the motor in the event that a short circuit occurs inside the motor (column 1, lines 13 – 19).

Response to Arguments

14. Applicant's arguments with respect to claims 24 – 39 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any


extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Surekha Vathyam whose telephone number is 571-272-2682. The examiner can normally be reached on 7:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam X. Nguyen can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SV/
2 October 2007


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